

REMARKS

A. Claim Rejections 35 U.S.C. § 103

1. Claims 1-10 are patentable over Freeman and Brucker

The Examiner has maintained the rejection of Claims 1-10 under 35 USC §103(a) as being unpatentable over U. S. Patent No. 6,306,114 to Freeman et al. ("Freeman") in view of U. S. Patent No. 6,296,657 to Brucker ("Brucker"). The basis for the Examiner's rejections was described in the previous response. In that response, Applicant advanced the arguments that Freeman disclosed valves which inherently allow flow in one direction and that Brucker's teaching of gel foam was incompatible with Freeman's valves. Applicant thanks the Examiner for addressing these arguments in the present Office Action and submits the following remarks.

First, the Examiner's concludes that the limitation regarding the sealing member sealing the lumen from fluid flow in "either direction" could be interpreted to apply to one direction *or* the other and that Freeman's valves do prevent fluid flow in one direction. As indicated in the previous response, Applicant's intention was to characterize the sealing member as substantially sealing the lumen from *both* directions. Therefore, to address the point raised by the Examiner and to clarify the claims, Applicant has now amended the claims to specifically state that the sealing member substantially seals the plug member lumen from the fluid flow in a proximal to distal direction and a distal to proximal direction.

As discussed in the previous response, allowing fluid flow in one direction is critical to the purpose of Freeman's device. Accordingly, Applicant respectfully submits there is no motivation to change the sealing member of Freeman so that it prevented fluid flow in both directions. Indeed, to do so would render it unsuitable for its purpose, making it inappropriate to base an obviousness rejection on the Freeman reference.

Second, Applicant respectfully disagrees with the Examiner's conclusions regarding Brucker's applicability to Freeman. With regard to this issue, the Examiner states that Brucker's teaching of an expandable foam material "would not necessarily prevent valve function."

However, the Examiner acknowledges that the Brucker foam “remains flowable when the device is placed in the wound.” As such, Applicant submits that a material which is flowable does not have the necessary structural properties to function in the valves disclosed by Freeman. Freeman discloses conventional “flapper” valves. In order to operate, the flapper material must have sufficient integrity to rest on the remaining valve structure and resist fluid pressure in order to prevent flow in one direction as required. The Examiner has provided no reasoning that would indicate a “flowable” expandable foam would have the necessary characteristics. Indeed, one of skill in the art would recognize that a flapper formed from “flowable” material would deform, allowing the flap to swing in either direction, and would not prevent flow in one direction. Accordingly, Applicant respectfully reiterates that there would be no motivation to combine Brucker’s flowable foams with Freeman’s valves, as doing so would render the valves unworkable.

For these reasons, Applicant requests that the Examiner withdraw the §103 rejection of Claims 1-10 over Freeman in view of Brucker.

2. Claims 11-18 are patentable over Freeman, Brucker and Hermann

Next, the Examiner maintained the rejection of claims 11-18 under 35 USC §103(a) as being unpatentable over Freeman and Brucker as discussed above, further in view of U. S. Patent No. 5,871,474 to Hermann et al.(“Hermann”). The Examiner cites Hermann for its teaching of a tapered lumen and contends that it renders the use of a sealing member comprising a coil of material obvious.

In light of the above discussion regarding Freeman’s failure to suggest a sealing member that substantially seals a lumen in both directions and the unsuitability of combining Brucker’s foams with Freeman’s valves, Applicant submits that Hermann teaching does not compensate for these deficiencies. Thus, Applicant requests that the Examiner reconsider and withdraw the § 103 rejection of Claims 11-18 over Freeman in view of Brucker and Hermann.

3. Claims 19-20, 22-25, 27-28, 32-35 and 37 are patentable over Freeman, Brucker and Atkinson

Next, the Examiner maintained the rejection of Claims 19-20, 22-25, 27-28, 32-35 and 37 under 35 USC §103(a) as being unpatentable over Freeman and Brucker as discussed above in view of U. S. Patent No. 6,645,225 to Atkinson (“Atkinson”). The Examiner supplements the teachings of Freeman and Brucker discussed above with Atkinson’s disclosure of an elongate member lumen in communication with the plug member lumen and a second elongate member comprising a location indicator.

Applicant submits that the combination proposed by the Examiner fails to suggest a sealing member that seals the lumen from fluid flow in both directions. As discussed above, Freeman requires the use of a valve that permits fluid flow in one direction. As such, the teachings of Brucker and Atkinson do not overcome this deficiency, particularly in view of the unsuitability of combining Brucker with Freeman discussed above. Since there is no motivation to combine the references in order to achieve a sealing member that seals the lumen from fluid flow in both directions, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of claims 19-20, 22-25, 27-28, and 32-35.

4. Claims 26, 31 and 36 are patentable over Freeman, Brucker, Atkinson and Sepetka

The Examiner then rejected Claims 26, 31 and 36 under 35 USC §103(a) as being unpatentable over Freeman, Brucker and Atkinson as discussed above, further in view of U. S. Patent No. 5,814,062 to Sepetka et al. (“Sepetka”). The Examiner cites the Sepetka reference for its teaching of an activation element.

As with the above rejections, Applicant notes that the primary references fail to suggest the use of sealing member that seals the lumen against fluid flow in both directions. For the reasons discussed above, Freeman specifically teaches away from such a feature, so Sepetka cannot overcome this deficiency. For these reasons, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 26, 31 and 36.

5. Claims 29 and 30 are patentable over Freeman, Brucker, Atkinson and Davis or Sommercorn

Finally, the Examiner rejected claims 29 and 30 under 35 USC §103(a) as being unpatentable over Freeman, Brucker and Atkinson as discussed above, further in view of U. S. Patent No. 6,143,004 to Davis (“Davis”) with respect to Claim 29, and further in view of U. S. Patent No. 6,494,848 to Sommercorn et al. (“Sommercorn”) with respect to Claim 30. The Examiner cites Davis for its teaching of a bleed back lumen and Sommercorn for an expandable member that provides tactile feedback for the location of the distal end of an elongate member.

As discussed above, Applicant submits that the primary references fail to suggest the use of sealing member that substantially seals the lumen from fluid flow in both direction. The secondary references Davis and Sommercorn cannot compensate for this deficiency since their teachings do not include any structure that corresponds to the plug member. Further, Freeman specifically teaches away from the use of a valve that obstructs flow in both directions. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the § 103(a) rejection of Claims 29 and 30.

B. Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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